

Having described my invention, I claim:

Sub B1
5 (1) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day as a single dose for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation exhibiting an *in vivo* stair-stepped absorption profile when a convoluted plasma curve for nicotinic acid released from the intermediate release nicotinic acid formulation is deconvoluted using the Wagner-Nelson method, wherein the stair-stepped absorption profile is generally characterized by three phases in which

up to about 19% of the nicotinic acid dose administered is absorbed between about 1 and about 4 hours following ingestion at the end of the first phase;

between about 78% and about 100% of the nicotinic acid dose administered is absorbed between about 4 and about 8 hours following ingestion at the end of the second phase; and

between about 86% and about 100% of the nicotinic acid dose is absorbed between about 5 and about 9 hours following ingestion at the end of the third phase.

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15 (2) An intermediate release nicotinic acid formulation of claim 1, wherein the nicotinic acid absorption mean for the three phases is:

about 6% of the nicotinic acid dose administered is absorbed at about 2.3 hours following ingestion at the end of the first phase; and

20 at least about 91% of the nicotinic acid dose administered is absorbed at about 7.3 hours following ingestion at the end of the second phase.

Sub B2
25 (3) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day as a single dose for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation exhibiting an *in vivo* stair-stepped absorption profile when a convoluted plasma curve for nicotinic acid released from the intermediate

release nicotinic acid formulation is deconvoluted using the Wagner-Nelson method, wherein the stair-stepped absorption profile is generally characterized by three phases in which

nicotinic acid is absorbed at a rate of up to about 9% of the nicotinic acid dose administered per hour between about 1 and about 4 hours following ingestion at the end of the first phase; and

nicotinic acid is absorbed at a rate of between about 14% and about 26% of the nicotinic acid dose administered per hour between about 5 and about 8 hours following ingestion at the end of the second phase.

(4) An intermediate release nicotinic acid formulation of claim 3, wherein the nicotinic acid absorption rate mean for the first and second phases is:

about 3% of the nicotinic acid dose administered per hour at about 2.3 hours following ingestion at the end of the first phase; and

about 19% of the nicotinic acid dose administered per hour at about 7.3 hours following ingestion at the end of the second phase.

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